

Operating Instructions SCOPE-CLEANER S20



CE 0120



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⚠ **Note** ⚠

The SCOPE-CLEANER S20 has been designed exclusively for the disinfection of flexible endoscopes.

Read the Operating Instructions before using this disinfection equipment.

⚠ **Caution** ⚠

The owner is responsible for ensuring that the equipment functions are all working properly and that it meets hygiene requirements.

In addition the owner is responsible, that only personnel use or maintain this unit that are trained in usage and safe handling of this unit.



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Read the operating instructions

Read the operating instructions before using the **SCOPE-CLEANER S20** for the first time and familiarize yourself with the functions and mode of operation of the unit and accessories.

Failure to comply with these operating instructions may result in injury to patients, users and maintenance personnel, and may also result in damage to the unit or endoscope, or the unit and endoscope may stop working completely.

Store the operating instructions near the unit so that all users have access to the instructions at all times.

Technical modifications

G-Flex Europe S.P.R.L reserves the right to modify and upgrade the unit without prior notice. Illustrations and descriptions in this manual, therefore, may differ from the actual unit.

Accessories

Special accessories, as listed in Appendix II of this manual, are required to operate the **SCOPE-CLEANER S20** in line with its intended purpose.



Note

Please pay particular attention to sections preceded by this symbol: 



Danger

Instructions for avoiding injury to patients, users, maintenance personnel or others.



Caution

Information on the proper function and use of the unit and accessories



Note

Special information and recommendations for operation, installation and maintenance of the unit and accessories.



Safety Instructions

Liability

Disclaimer:

G-Flex Europe SPRL is not liable for any damage, direct or consequential, which occurs under the following conditions:

- the unit or accessories are operated, treated or maintained inappropriately;
- the instructions and specifications set out in this manual are not observed;
- repairs, adjustments or modifications to the unit or accessories have been carried out by unauthorized persons;
- the unit has been opened by unauthorized persons;
- the prescribed inspection and maintenance intervals are not observed.

Authorized Service Technicians



Caution

Only service technicians certified by G-Flex Europe SPRL are authorized to carry out repairs, adjustments or modifications to the unit and accessories. Authorized service technicians are trained and certified exclusively by G-Flex.

Proper use of the equipment



Caution

The **SCOPE-CLEANER S20** unit should only be operated in accordance with its intended purpose in the manner described in this manual.

Space requirements



Note

Before installing the **SCOPE-CLEANER S20**, ensure that there is sufficient space on the contaminated side of the reprocessing room for the installation of the unit and that all the required mains and other supplies including a drain pipe are available (see Chapter 3 “Using the equipment for the first time”).

To sterilize the water filter for the **SCOPE-CLEANER S20**, you will need a steam sterilizer (autoclave, see Chapter 5 “Service and maintenance”) which meets the requirements of EN 13060, process cycle Type B.

Installation

Installation must be carried out by a professional installation company. When installing the equipment, the following standards must be applied: EN 1717 and DIN 1988-4. On-site training is provided by G-Flex Europe SPRL or a medical equipment consultant authorized by us.



Service and maintenance



Caution

Safe operation of this unit can only be guaranteed if the maintenance and service instructions described in this manual are observed at all times.

Training

On-site training is provided by G-Flex Europe SPRL or a medical equipment consultant authorized by us.



Caution

In addition the owner is responsible that only personnel uses or maintains this unit that is trained in usage and safe handling of this unit.

Functional test



Caution

Before use, check the equipment to ensure all components are in place and that the unit is working properly. Before using the unit for the first time and after repairs have been carried out always check that the equipment has been installed properly. Function checks are listed in Chapter 3 under "Functional test".



Danger

➤ Unauthorized opening of the unit

Live components become exposed when the unit is open and can cause electric shocks if touched. Never open the unit yourself. The unit may only be opened by an authorized G-Flex Europe SPRL service technician.

➤ Penetration of liquids

Liquid entering the unit may prevent the unit from working properly and/or present the risk of electric shock. Fluids should therefore never be permitted to enter the unit. Always avoid placing fluids in the vicinity of the electrical components.

Do not operate if liquid has penetrated the unit.

➤ Operation in explosion-proof areas

The unit is not explosion-proof. Operation in areas with explosive gases can lead to severe damage and cause injury.

➤ Use of inappropriate accessories

The use of inappropriate accessories can cause the unit to operate incorrectly, which may result in injury to patients, users and service technicians. Use only accessories specified as being compatible with the **SCOPE-CLEANER S20** (see Chapter 8 " Technical specifications ").

➤ Faulty fuses

When replacing a faulty fuse please ensure the new fuse corresponds with the specifications displayed on the unit or set out in this manual.

The use of incorrect fuses can cause the unit to function incorrectly and may result in injury to users and others.



➤ **Faulty unit**

It is generally dangerous to operate a faulty unit. Do not operate the unit if you suspect it to be faulty or if it is known to be faulty. Make sure the unit cannot be operated until checked by an authorized technician.

➤ **Not trained Personnel**

Not trained personnel could endanger themself or someone.

The owner is responsible to regularly train the user / operators of this unit. Especially personnel that are in use of toxic chemicals, gas or exposure of fumes must be regularly trained comprehensively in the procedure instructions. Those procedure instructions must contain relevant information about possible dangers of health, national guidelines for safe usage and special procedures in case of leaking active agent. According to EN 61010-2-24 this trainings must be documented with lists of attendants and verification protocols for expert knowledge.

Additional safety instructions specific to this unit are described in other sections of this manual.

2. Intended use and purpose

The **SCOPE-CLEANER S20** is used for semi-machine-based hygienic processing of waterproof flexible endoscopes made by OLYMPUS, FUJINON, PENTAX and STORZ which have a maximum of five additional channels (jet channel, air channel water channel, biopsy channel, suction channel).

The units are equipped with a channel monitoring system which detects blockages in the endoscope channels to be cleaned or disinfected (monitoring only applies to air/water and suction channels).

As additional options there is a permanent Leakage-Test implemented. To activate the test, press the button in the **Process Parameters** menu using the touch-panel (see Chapter 4 "Operating the SCOPE-CLEANER S20").

The **SCOPE-CLEANER S20** is equipped with a sterile water filter which enables the water required for processing the endoscopes to be drawn from the normal mains drinking water supply.

The unit is supplied on a floor-mounted cabinet.





Note

Cleaning and disinfection must be accurately documented in a traceable manner. Supplied with the unit is an optional Zebra TLP2844 Printer system to enable you to document this phase, which should be attached to the **SCOPE-CLEANER S20**. The printout must then be stored in a suitable place; preferably inside the service manual or in the file for the patient on whom the endoscope was used.

Listed in the label printing:

- The quantity and the time of each cycle;
- The hour and date for the procedure;
- The code of the device;
- The name/code of the responsible user ;
- The name/code of the patient;
- The disinfection life time;
- The total cycle realized by the unit;
- The unit ID;



Note

The unit has the option of storing information of the disinfection process using a USB storage device (USB Flash Drive).

Recommended standard procedure

The recommended standard procedure consists of leakage test, prewashing, disinfection and neutralizing:

- 1 **Leakage test: 2 min.**
- 2 **Prewash: 4.5 min including 1min blow out.**
- 3 **Disinfection cycle: freely selectable+ 4 min (filling and emptying) including 1min blow out.**
- 4 **Neutralization: 7 min including 2 min blow out.**

Total time = 18 min + disinfection time



Note

Perform the self-disinfection cycle without an endoscope once per working day after endoscope processing has completed and if the machine has not been used for 12 hours (refer to the Chapter entitled "Self-disinfection cycle for the **SCOPE-CLEANER S20**")



Contraindications:

Do not use the **SCOPE-CLEANER S20** for reprocessing endoscopes if no information regarding suitability for use with **SCOPE-CLEANER S20** is available.

Do not use the **SCOPE-CLEANER S20** for hygienic processing of endoscopes equipped with additional auxiliary channels, i.e. more than the five channels indicated (jet channel, air/water channel, biopsy 1 and 2 channel, suction channel).

If in doubt, please contact the manufacturer of the endoscopes or G-Flex Europe SPRL or a service engineer authorized by us.

3. Using the unit for the first time

Check the inventory

- Check the unit and accessories immediately upon delivery to ensure all components are included and look for any visible external damage.

The following components should be supplied with the unit (customized orders may differ somewhat):

– SCOPE-CLEANER S20 incl. Floor-mounted,



– 15-l tank for disinfectant with filter and quick-release couplers in the lid (spare part number 7615-A00)



- Enzymatic tank with quick-release couplers in the lid
(spare part number 7885-075)



- Connection tube to drinking water mains
with dirt trap
(spare part number 7002-511)



- Sterile water filter
(spare part number 11-0100)



Note

- The sterile water filter must be autoclaved before first use and thereafter once per week
- After it has been autoclaved
- 10 times or if it has been used for a maximum of 4 weeks without processing, the sterile water filter / Pall filter must be replaced.



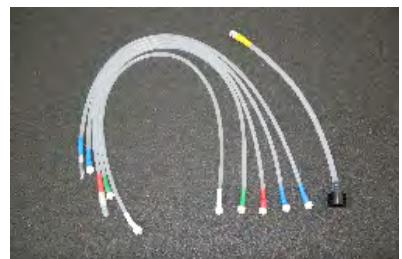
- Filling tube for connecting to the sterile water filter
(spare part number 7006-350)



- Cold device connection cable with earthed plug
(spare part number 5020-010)



- 6 connection tubes in a connection set for SCOPE CLEANER S20
(spare part number 7600-NS0 or 7600-NS1)



- Connection tube for leakage test:
The connection tube connections are adapted to the specific endoscope.



- Detailed photo of the leakage tester cap PENTAX
(spare part number 7526-PE-RF-SET)



- Detailed photo of the leakage tester cap
OLYMPUS
 (spare part number 7526-OL-SET)



- Detailed photo of the leakage tester cap
FUJINON
 (spare part number 7526-FU-SET)



- Optional:
PALL prefilter excluding holder
 (spare part number 11-1005)



Note

The maximum operating temperature of the liquid to be filtered must not exceed 40°C.



- Optional:
PALL prefilter cartridge, packaged
 (spare part number 11-1105)



Note

The maximum operating temperature of the liquid to be filtered must not exceed 40°C.



– Optional:

Wall holder for PALL prefilter
(spare part number 11-1006)



– Optional:

Gunmetal double nipple ¾“
for PALL prefilter
(spare part number 11-1007)



– Optional:

Zebra printer
(spare part number TLP2844)



– Operating Instructions



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Installing the SCOPE-CLEANER S20

Overview of the unit



Device dimensions (cm)



Setting up the unit

Ensure the chosen operating environment for the **SCOPE-CLEANER S20** is dry and has a relative air humidity of no more than 70% and an ambient temperature between 10°C and 35°C.

Floor-mounted unit

SCOPE-CLEANER S20 place the cabinet on an even floor and use the four adjustable screw feet fitted to the cabinet to ensure the unit cannot wobble.



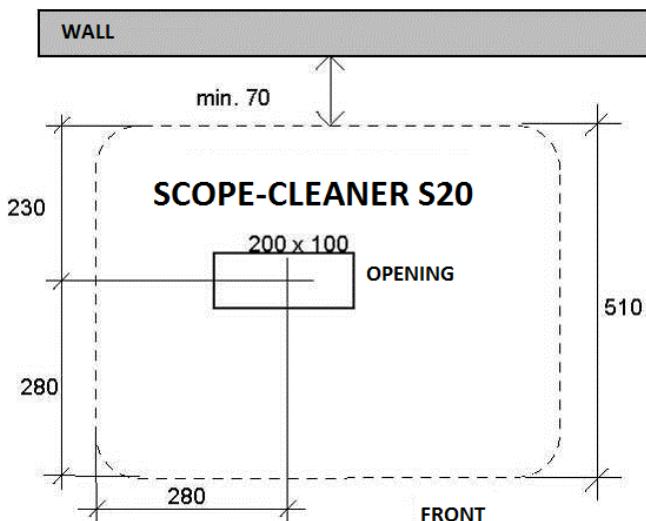
Operating the unit on a bench

Make sure that the ergonomic principles are respected. Is advised that the bench needs to be 900 mm from the floor, but it could be adjusted from place to place.

The width and depth of the bench were calculated to ensure that the **SCOPE-CLEANER S20** is firmly positioned on the bench while it is important to maintain a minimum distance of 70 mm from the walls.

The bench needs to have an opening (200 X 100 mm) for the drain system.

The drain leading to the building's sewers must not be higher than 450 mm from the floor.



Connecting to the water supply and drain

The **SCOPE-CLEANER S20** is connected to a 3/4" drinking water mains supply using the combined connection tube and dirt trap supplied with the unit.



- The maximum water pressure in the mains water tube should not be more than 5 bar, but should be more than 2,6 bar. If the pressure is greater, install a pressure reducer.



- If the unit is connected to the mains water supply we recommend using an additional aquastop device to cut off the water supply to the unit if there is a burst pipe.
- The drain hose must have a uniform slope to ensure liquid can drain completely with no sagging in the hose, which would cause liquid to remain in the hose.





Note

- The **SCOPE-CLEANER S20** has a built-in device which prevents any contaminated fluid in the device from being returned into the drinking-water supply. When performing daily surface disinfection work on the **SCOPE-CLEANER S20**, ensure under all circumstances that there is no transfer of infection into the filling tube from contaminated utensils (e.g. swabs, cloths), which would contaminate the drinking water. The professionals installing the equipment will be able to advise you on the EN 1717 and DIN 1988-4 standards, which must be adhered to. We recommend that you also fit an aqua-stop system which blocks off the inflow of water if one of the tubes springs a leak or bursts.
- Depending on the water quality of the water supply (domestic water) we recommend a PALL prefilter (optional) to prefilter coarse particles.



Note

- The **SCOPE-CLEANER S20** drain tube (silicone tube tapered to be wider at the end) is also connected to the normal sewage system for your building. The drain leading to the building's sewers must not be higher than 450 mm from the floor.
- The drain tube must have a uniform slope to ensure liquid can drain completely with no sagging in the tube, which would cause liquid to remain in the tube.

Electrical connection

The **SCOPE-CLEANER S20** is connected to the mains power supply via the "cold device connection cable" supplied.



Caution

- Check the label on the back of the unit to ensure that the mains voltage is appropriate. If the mains voltage is incorrect the unit may not function properly or could be damaged.
- The maximum power consumption of the **SCOPE-CLEANER S20** is 3,15A. It is recommended that the **SCOPE-CLEANER S20** is connected on a separate fuse to the mains.



Danger

- The unit must be connected to the mains via an earthed contact.
- The unit is not explosion-proof. Do not operate the unit in an environment which may contain explosive gases.

The **SCOPE-CLEANER S20** may be used as soon as it has been installed correctly. The procedures outlined below should be carried out the first time the unit is used and then at regular intervals during normal operation.



Controls

- Main switch



(Switch position “I”)

*The main switch will show green.
The display will show the main menu.*

- Touch-panel

All machine controls are made through the Touch Screen panel



Connection on back and right side

- Shrouded 3-pin plug with mains fuses.
To change the mains fuses, disconnect the unit from the mains and use a small screwdriver to extract the fuse holder and the fuses.
Replace with new ones.
- The voltage selector (230V – 115V).



- The **SCOPE-CLEANER S20** has the voltage supply 230V and an optional version with voltage selector switch (230V – 115V).



- Make sure to know the voltage supply. If the local voltage is 115V, request the **SCOPE-CLEANER S20** with the voltage selector switch (230V-115V). Supply a voltage different from that defined by the voltage selector switch (230V-115V) might cause the unit to malfunction or even damage it. If any doubt persist, contact the G-Flex Europe SPRL or a professional authorized by us

- 1 – USB connection for printer or USB storage device (USB Flash drive).



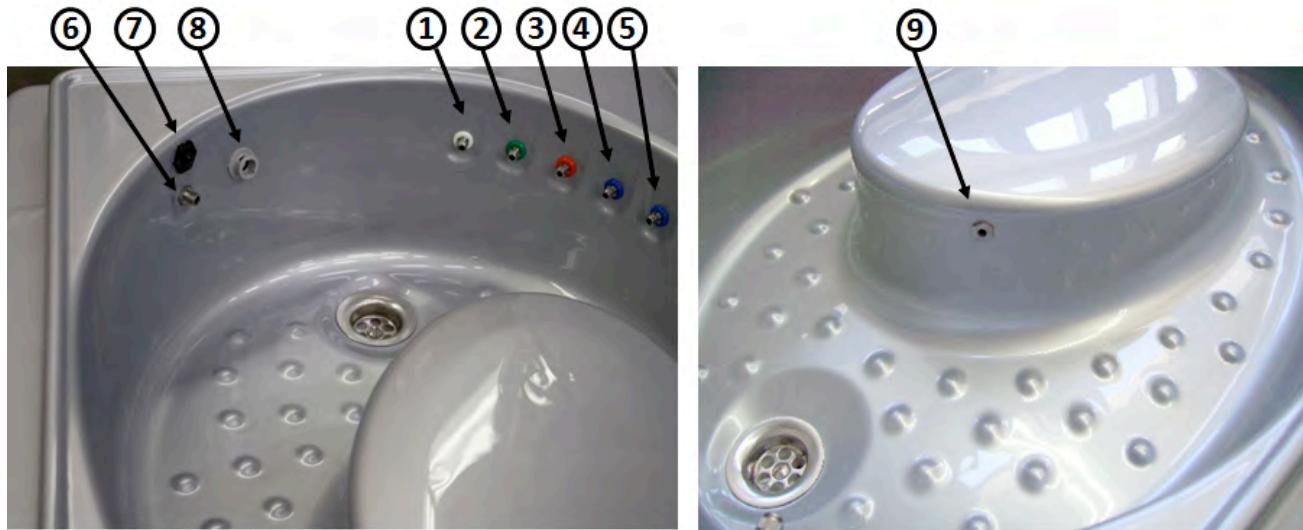
Openings for adjusting on front side

- 1 – Opening for adjusting channel monitoring

Left side: Suction channel
Right side: Air/water channel



Connections in disinfection tank



1	LL-W small (white)	jet channel
2	LL-W small (green)	biopsy channel
3	LL-W small (red)	suction channel
4	LL-W small (blue)	air/water channel
5	LL-W small (blue)	biopsy channel 2
6	LL-W big	suction pipe
7	Level sensor (black)	
8	Leakagetest connector	
9	Additional connection for dosing enzymatic cleaner	



Functional Test

- To perform the functional test, proceed as follows:
 - Check all connections to the drinking water, electrical supplies and the drains. Ensure they are firm.
 - Check if the sterile water filter has been autoclaved and correctly connected.
 - Open the drinking water stopcock.
 - Switch on the unit with the main switch. (Switch position “I”)



The main switch will show green and the display will show the main menu.

- To check the pumps and valves, proceed as follows:
 - Tap the Options button at the main screen.
 - Tap the Output Control button.
 - To check the pumps and valves, tap the corresponding button.



Nota

- The access to Output Control could be protected by password.



Warning

- DO NOT use the unit for purging or disinfecting endoscopes if the functional test has NOT been successfully completed. If in doubt, please contact G-Flex Europe SPRL or a service engineer authorized by us.



4. Operating the SCOPE-CLEANER S20

Functional tests & routine checks to be performed on every working day

For the functional test, proceed as follows:

- Check all connections to the drinking water, electrical supplies and the drains. Ensure they are firm.
- Check if the strainer has been autoclaved and correctly connected.
- Open the drinking water stopcock.
- According to the supplier recommendation, verify the disinfection and enzymatic solution validity by inserting the tag directly in the opening of the gallon lid (See picture below)
- Switch on the unit. The switch is on the right side.



Reprocessing endoscopes using the SCOPE-CLEANER S20



- Employee health and safety regulations must be observed during all procedures which require contact with disinfectants or in relation to the cleaning and disinfection of endoscopes.
- Throughout all the steps outlined below, it is essential to wear protective clothing, i.e. disposable gloves, mouth and nose masks, goggles and a waterproof protective coat or apron.
- Because the air in the reprocessing room may contain a high level of disinfectant fumes, there must be adequate ventilation or air extraction.
- Since it is common for contaminated liquids to splash, it is essential to perform a thorough surface disinfection procedure afterwards.





Note

- The SCOPE-CLEANER S20 has a security sensor that check if the door is open during the process. An alert message will show up in the touch screen panel when the sensor is activated.



Note

- When operating the **SCOPE-CLEANER S20** and while processing flexible endoscopes, observe the general requirements relating to handling endoscopes:
 - Robert Koch Institute:
 - "Hygiene requirements when processing medical equipment".
 - "Hygiene requirements when processing flexible endoscopes and additional instruments used in endoscopy".
 - "Hygiene requirements as applied to the design and construction of endoscopy instruments".
 - Employees' safety organizations: Organic substances
 - Regulations relating to suppliers of medical products
 - Drinking water regulations

Preparative tasks

Preparing the sterile water filter

Before using the device for the first time, the sterile water filter and the feed pipe and silicone tube which connect to it must be sterilized in an autoclave.

The sterilization method is described in the "Service and Maintenance" section.



Note

- The sterile water filter must be autoclaved before first use and thereafter once per week.
- After it has been autoclaved 10 times or if it has been used for a maximum of 4 weeks without processing, the sterile water filter / Pall filter must be replaced.



Preparing disinfection solution



Note

- Please refer to the operating instructions supplied with your endoscope for information on disinfectants which are approved for use with endoscopes.
- If you want to use a disinfectant which is not expressly recommended for use by the endoscope manufacturer, please obtain written evidence of compatibility from either the endoscope producer or the disinfectant manufacturer. Instructions issued by the manufacturer of the endoscope on material compatibility must be followed exactly.
- Use only disinfectants whose germicidal, fungicidal, mycogermicidal and virucidal effectiveness have been verified. All disinfectants approved in accordance with DIN EN standards on disinfecting surgical instruments and/or in accordance with the standard methods of the VAH are considered suitable. Efficacy in destroying viruses must be separately demonstrated. Observe the recommendations issued by RKI on the testing and declaring the effectiveness of disinfectants in combating viruses.
- The following table provides guidelines for formulating disinfectants of various concentrations with a total volume of 17 liters:

Concentration of solution	2.0%	3.0%	4.0%	5.0%	10.0%
Water [ml]	16660	16490	16320	16150	15300
Concentrated disinfectant agent [ml]	340	510	680	850	1700



Caution

- After the disinfectant reservoir has been filled, make a note of the date when the disinfection solution was mixed in a clearly visible, suitable place and in the service manual (service manual table, refer to the Appendix).
- The disinfectant should be changed according to the manufacturer's instructions or sooner if there is visible contamination. We recommend replacing the disinfectant after one week at the latest. Where colonoscopes are to be processed, the disinfectant solution must be changed daily or, at the latest, every second day.
- When the disinfection solution is replaced, the disinfectant reservoir itself must be thoroughly cleaned and disinfected manually using suitable cloths and surface disinfectant.
- The suction filter in the disinfectant reservoir must be replaced at least every 14 days.
- The date of the last filter change must be noted in a clearly visible position and in the User Information Pack (Service Manual Table, see Appendix)





Caution

- Please follow the manufacturer's instructions exactly when preparing the disinfectant solution and observe the specified concentration and exposure times.

If the exposure time is too short the disinfection process will be negatively affected while a long exposure time can damage the endoscope.



Caution

- The suction pipe and strainer guarantee that the liquid (disinfection solution) flows through the endoscope channels unhindered. Please ensure the suction tube is connected properly and that the filter is in the correct position on the floor of the disinfectant reservoir.
- The filter on the suction tube must be replaced at the latest every 14 days. The date when the filter was last changed has to be documented in the Maintenance book.



Note

We recommend using a WG enzymatic detergent solution. An enzymatic detergent concentration of 0.5 % – 1 % is sufficient for use with **SCOPE-CLEANER S20**. If the endoscope is heavily soiled the concentration may be increased to 5 %. The following table provides guidelines for the preparation of enzymatic solutions of various concentrations for disinfectant reservoirs of various sizes:

Concentration of solution	0.5%	1.0%	2.0%	3.0%	5.0%
Concentrated enzymatic detergent [ml]	75 ml	150 ml	300 ml	450 ml	750 ml
Quantity of Enzymatic per liter	5 ml	10ml	20ml	30ml	50ml

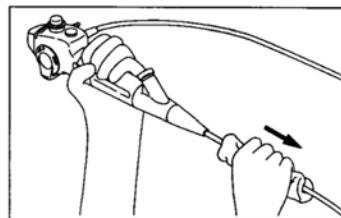


Endoscope reprocessing in accordance with the reprocessing plan (refer to Appendix VI)

Precleaning the endoscope directly after an endoscopic examination

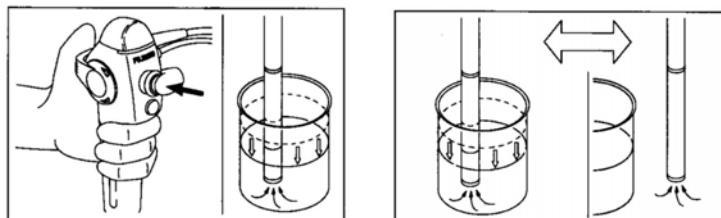
The prewash will be performed directly on the light source in subsequent to the examination. The outer coating of the insertion tube has to be cleaned as described by the endoscope supplier with a lint-free fabric saturated with cleaning solution, starting on the control element to the distal end.

G-Flex Europe SPRL has specially developed cleaning sponges soaked in a special enzymatic cleaning agent. Further details are available from the main GFlex catalogue or your authorized supplier.



Sufficiently enzymatic cleaning solution has to be sucked through the channel system by actuating the suction vent. All accessible channels has to be rinsed multiple times to prevent any incrustation or pharmacological debris building up inside the channels which may not be removable later.

Separate the endoscope from the processor / light source, optical rinsing system and suction pump. Contact safety caps to the contacts on the supply jack and vents and disconnect loose components.



The disconnected and capped endoscope ha to be stored and transported to the reprocessing room in a closed container (e.g. a pan with a lid). Then place the endoscope in a sink filled with a detergent solution.

Transporting the endoscope in a closed container avoids contaminating the immediate environment.



Manual cleaning in the processing room



Caution

- Before performing manual cleaning, it is essential to carry out a leakage test on the endoscope concerning the instructions of the endoscope manufacturer.
- Alternatively you could perform a leakage test by using the LEAKAGE:MASTER.

The next cleaning stage is carried out on the dirty side of the reprocessing room since spray from the cleaning fluid can contaminate surfaces.

To prevent internal residues from hardening, clean the outside and on the vents entries of the endoscope carefully with a brush according to the manufacturer's instructions.



Carry out each individual step in accordance with the instructions issued by the manufacturer of the endoscope.



Caution

- After cleaning the endoscope with the brush, rinse the channels with potable water and then blast with air to avoid interaction between the detergent and disinfectant solutions.
- Any fluid remaining in the channels could dilute the disinfectant solution thereby reducing its efficacy.



Danger

- If the endoscope is not cleaned properly, thorough disinfection cannot be guaranteed.
- All cleaning stages, particularly brushing the endoscope channels, should be performed with the endoscope fully submerged in the detergent solution to avoid sprays of contaminated fluid.
- Brushes used for cleaning endoscopes must be cleaned and disinfected in accordance with RKI guidelines on non-critical medical equipment. The brushes should be cleaned and disinfected in an ultrasonic bath after each use to avoid cross contamination. At the end of the working day, after cleaning and disinfection, the brushes should be stored in a dry area which is protected from contamination.



A fresh batch of detergent solution must be prepared at least once per working day. If the solution looks dirty or has been contaminated with organic waste, the detergent should be replaced immediately with a fresh batch.

The cleaning sink must be thoroughly cleaned and disinfected daily.

Connecting the endoscope to the SCOPE-CLEANER S20



- The manner in which various endoscope models are attached to the **SCOPE-CLEANER S20** is illustrated in Appendix I.
- Connect the endoscope channels via the connection tubes (= channel tubes) to the disinfectant tank rinse adapters. Observe the color-coded markings on the connection tubes (see table below)

Endoscope Channel	Color of Channel Tube	Color, Location of Tank Connection
Jet Channel	White	White, Far Left Connection
Biopsy Channel	Green	Green, 2nd Connection from Left
Suction Channel	Red	Red, 3rd Connection from Left
Air/Water Channel	Blue	Blue, 4th Connection from Left
Extra Channel	Blue	Blue, 5th Connection from Left



Connecting the suction tube with filter

- Connect the "Suction pipe and strainer" (color-coded yellow) to the connection on the tank.



Normally, the suction pipe remains in the tank and is connected up when the unit is commissioned next or the strainer is changed.

For information on repairing the fault please refer to the "Troubleshooting" section.



Caution

- The suction tube and strainer guarantee that the liquid (water/disinfection solution) flows through the endoscope channels unhindered.
Please ensure the suction tube is connected properly and that the filter is in the correct position on the floor of the disinfectant tank.
- The filter in the suction tube must be replaced at the latest every 14 days.



Caution

- Apart from channel openings on the distal end of the endoscope, no air bubbles should emanate from any part of the endoscope.
Air bubbles forming on any other part (e.g. on the control head) are an indication that the endoscope is leaking.
- If you notice air bubbles, tap the Stop button from the control panel display and confirm to stop the process. Wait till the reservoir is empty and then inspect the endoscope.

For information on repairing the fault please refer to the "Troubleshooting" section.



Caution

- Please follow the manufacturer's instructions exactly when preparing the disinfectant solution and observe the specified concentration and exposure times.
If the exposure time is too short the disinfection process will be negatively affected while a long exposure time can damage the endoscope.



**Note**

- If the **SCOPE-CLEANER S20** were switched off when it is full or if there is a power outage while it is in use, it will be necessary, when the unit is switched on again, to drain off the fluid in the tank manually by selecting the Output Control from the Options Menu.

**Caution**

- The accordingly operation of the **SCOPE-CLEANER S20** is only allowed with closed disinfection tank cover.
- Please look out when opening or closing the disinfection tank cover on your hands, possible clamped parts of the endoscope or parts that are laying on the top of the disinfection tank cover.
- In Singe fault (i.e. loss of power or unit error) it is not allowed to open the disinfection tank cover without adequate preventive measures to avoid contact or contamination of the user / operator with disinfection agent or bacteria.

**Note**

- The functionality and efficiency of the **SCOPE-CLEANER S20** is independent of the water temperature. Therefore there is no need to mix hot and cold water. Water at room temperature coming directly from the water supply is enough.



Screen's Main Buttons

Main Buttons	
	Confirm
	Emergency Stop/ Cancel
	Start Process
	Home Screen
	Previous Screen
	Next
	Previous



4.1 Screens and Buttons Descriptions

➤ Initial Screen

Home Screen	
1	Configuration
2	Options
3	Catalog
4	Doubts
5	Start Process



➤ Configuration Screen

Configurations	
1	Process Parameters
2	Disinfectant Parameter
3	Filters Parameters
4	Self-Disinfection Parameter
5	Date & Time Adjust
6	Password
7	Machine's Information
8	Return Home



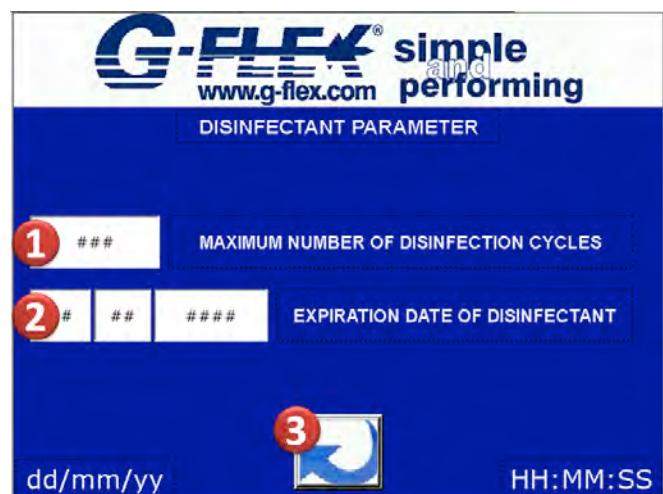
➤ Process Parameters

Process Parameters	
1	Quantity of Cleaning
2	Quantity of Enzymatic per liter (ml)
3	Quantity of (Pre)rising
4	Disinfection Time (min)
5	Quantity of Neutralization
6	Final Blow Out (seg)
7	Enable/Disable Leakage Test
8	Previous Screen



➤ Disinfection Parameter

Disinfection Parameter	
1	Maximum number of cycles
2	Expiration Date
3	Previous Screen



➤ Filters Parameters

Filters Parameters			
1	Autoclave Sterile Water Filter	##	####
2	Replace Sterile Water Filter	##	####
3	Replace Pre Filter	##	####
4	Previous Screen	##	####



➤ Self-Disinfection Parameter

Self-Disinfection Parameter			
1	Gap for self-disinfection (hour)	##	##
2	Self-disinfection time (min)	##	##
3	Previous Screen	##	##



➤ Adjust Date & Time / Password

A)



B)



A)

Adjust Date & Time	
1	Adjust Date & Time
2	Previous Screen

B)

Password	
1	Set Password
2	Previous Screen

➤ Options

Options Menu	
1	Output Control
2	Machine's Status
3	Change Disinfectant
4	Insert Users
5	Insert Devices
6	Device Status
7	Screen Calibration
8	Previous Screen



➤ Output Control

Output Control	
1	Turn On Enzymatic Pump
2	Turn On Disinfection Pump
3	Open Tank Valve
4	Turn On Compressor
5	Turn On Circulation Pump
6	Open Water Valve
7	Open Drain Valve
8	Open Depressurization Valve
9	Previous Screen



Configuring the unit before disinfection process



Note

- For the first time that the **SCOPE-CLEANER S20** is turned on, a buzzer and an alert message could be activated. It is necessary to set Date and Time, the parameter for the Self-Disinfection as well as the parameters of Disinfectant and Filters. If those configurations aren't set correctly, the unit can not alert properly the warning/alert messages.
- The sterile water filter must be autoclaved before first use and thereafter once per week.
- After it has been autoclaved 10 times or if it has been used for a maximum of 4 weeks without processing, the sterile water filter / Pall filter must be replaced.
- Please refer to the operating instructions supplied with your endoscope for information on disinfectants which are approved for use with endoscopes.
- If you want to use a disinfectant which is not expressly recommended for use by the endoscope manufacturer, please obtain written evidence of compatibility from either the endoscope producer or the disinfectant manufacturer. Instructions issued by the manufacturer of the endoscope on material compatibility must be followed exactly.
- Use only disinfectants whose germicidal, fungicidal, mycogermicidal and virucidal effectiveness have been verified. All disinfectants approved in accordance with DIN EN standards on disinfecting surgical instruments and/or in accordance with the standard methods of the VAH are considered suitable. Efficacy in destroying viruses must be separately demonstrated. Observe the recommendations issued by RKI on the testing and declaring the effectiveness of disinfectants in combating viruses.



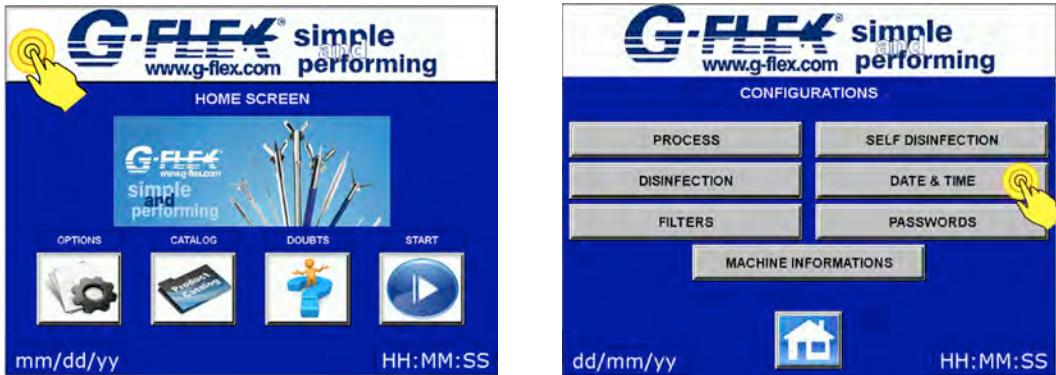
Caution

- After the disinfectant reservoir has been filled, make a note of the date when the disinfection solution was mixed in a clearly visible, suitable place and in the service manual (service manual table, refer to the Appendix).
- The disinfectant should be changed according to the manufacturer's instructions or sooner if there is visible contamination.
We recommend replacing the disinfectant after one week at the latest. Where colonoscopes are to be processed, the disinfectant solution must be changed daily or, at the latest, every second day.
- All the Parameter's Configuration might be exactly set according to manufacturer's instructions.



Configure Date/Time

➤ Tap the configuration button,  from the main screen and select DATE & TIME Button.

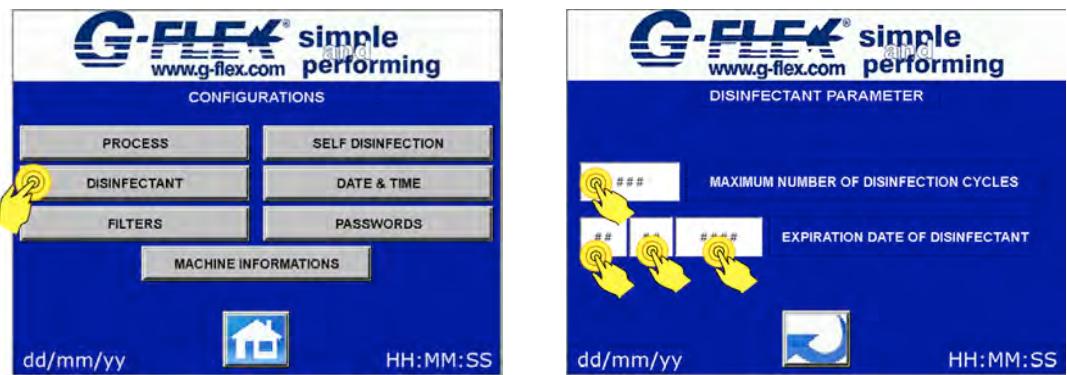


➤ Select the icon and set the date and time.



Configure Disinfection's parameters (expiration date)

➤ At the Configuration Screen tap the Disinfectant Button to set the parameter.
 • Enter the Maximum quantity of cycles and the Expiration date of Disinfectant.



Configure Filters's Parameters

- At the Configuration Screen tap the Filters Button to set the parameters.



- Enter the parameters of the next date to autoclave the sterile water filter (A).
- Enter the parameters of the next date to replace sterile water filter (B).
- Enter the parameters of the next date to replace pre filter (C).



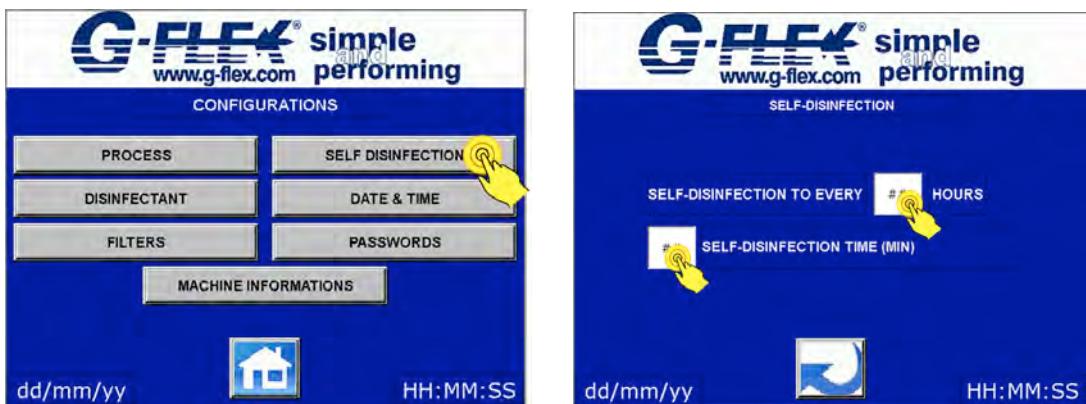
Note

- The sterile water filter must be autoclaved before first use and there after once per week.
- After it has been autoclaved 10 times or if it has been used for a maximum of 4 weeks without processing, the sterile water filter / Pall filter must be replaced.
- The **SCOPE-CLEANER S20** will alert the user that the date to autoclave or replace the sterile water filter or to replace pre filter have expired showing an alert messenger in the main screen (see Appendix IV: Error and warning messages).



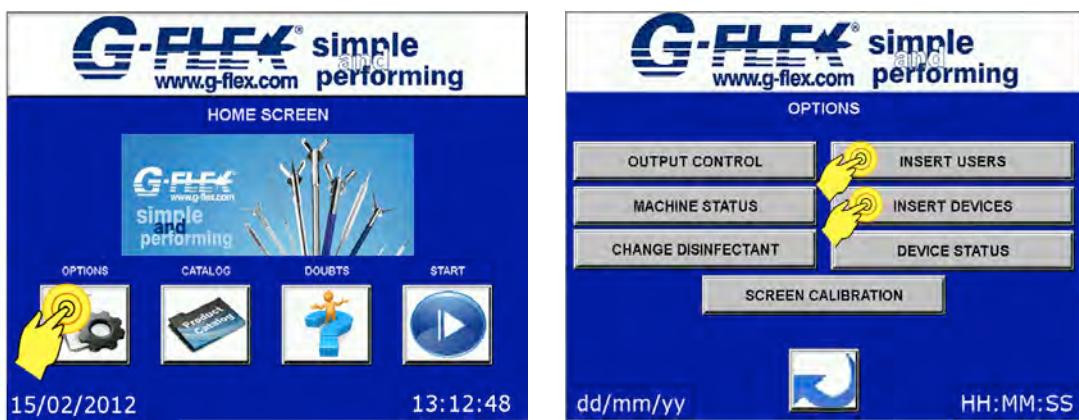
Configure Self-Disinfection's Parameter

- At the Configuration Screen tap the Self-Disinfection Button to set the parameters.
- Enter the parameters of the Self-Disinfection.



Insert Users and Devices

- Tap the Options Button at the main screen.
- Select Insert Users or Devices.



- Tap one of the positions to add a new Use or Device.
- A virtual keyboard will be enabled.
- Type the name/code of the Use or Device. To finish, tap the ENT.



➤ The process to insert devices and users are similar. The difference between them is the quantity of positions available. There are 15 positions for Users and 80 positions for Devices.



➤ The **SCOPE-CLEANER S20** has an internal counter to measure the quantity of cycle each device has been reprocessed. It helps to manage the next maintenance.



Processing endoscopes with the SCOPE-CLEANER S20

The SCOPE-CLEANER S20 is able to perform procedures that were previously selected in the Process Parameter Configuration.



Caution

- All the Parameter's Configuration might be exactly set according to manufacturer's instructions.
- Different sets, including the exposure time and/or inadequate dosage of disinfection solution, could negatively affect the process or damage the endoscope.

Recommended standard procedure

(Leakage Test, [Cleaning], Prerinsing, Disinfection, Neutralization)



Note

- If you performed enzymatic precleaning outside the **SCOPE-CLEANER S20** first, the unit allows you to run the automatic prewash before the disinfection operation to ensure that all the residues of cleansing agents are removed from the endoscope completely before the disinfection procedure begins. If the automatic prewash function in the **SCOPE-CLEANER S20** is used, it is not necessary to perform the rinse stage in the precleaning sink.
- Check all connections to the drinking, supplies and the drains. Ensure they are firm.
- Check if the strainer has been autoclaved and correctly connected.
- Open the drinking water stopcock
- Switch the unit via the main switch.

1. **Leakage test: 2 min**
2. **Prerinsing: 4.5 min including 1 min blow out.**
3. **Disinfection cycle: freely selectable+ 4 min (filling and emptying) including 1min blow out.**
4. **Neutralization: 7 min including 2 min blow out.**

Total time = 18 min + disinfection time (including 2 min blow out)



Additional enzymatic precleaning with the SCOPE-CLEANER S20



Note

- For particularly heavily contaminated endoscopes, the **SCOPE-CLEANER S20** offers the option of extending the process by adding an enzymatic precleaning followed by a flushing stage before disinfection.
- This extends the recommended standard procedure by 3.5 minutes + 1 minute blow out.

<ol style="list-style-type: none">1. Leakage test: 2 min2. Cleaning: 4.5 min including 1 min blow out.3. Prerinsing: 4.5 min including 1 min blow out.4. Disinfection cycle: freely selectable+ 4 min (filling and emptying) including 1min blow out.5. Neutralization: 7 min including 2 min blow out.
--

Total time = 22.5 min + disinfection time (including 2 min blow out)

Endoscope disinfection with SCOPE-CLEANER S20



Note

- The **SCOPE-CLEANER S20** is able to run just the Disinfection step followed by the Neutralization of the endoscope.

<ol style="list-style-type: none">1. Leakage test: 2 min2. Disinfection cycle: freely selectable+ 4 min (filling and emptying) including 1min blow out.3. Neutralization: 7 min including 2 min blow out.
--

Total time = 13 min + disinfection time (including 2 min blow out)

The following points apply:

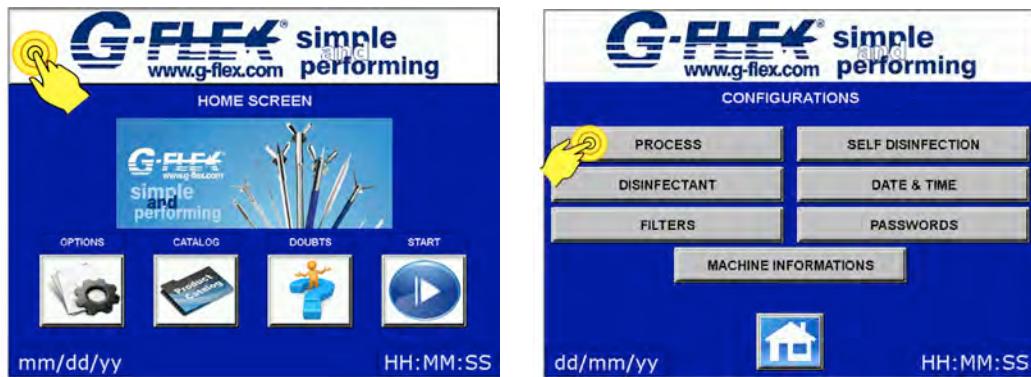
According to current guidelines, endoscopes must always be subjected to manual precleaning (wipe the endoscope, brush out all accessible channels and valve openings etc.)



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Setting Procedures

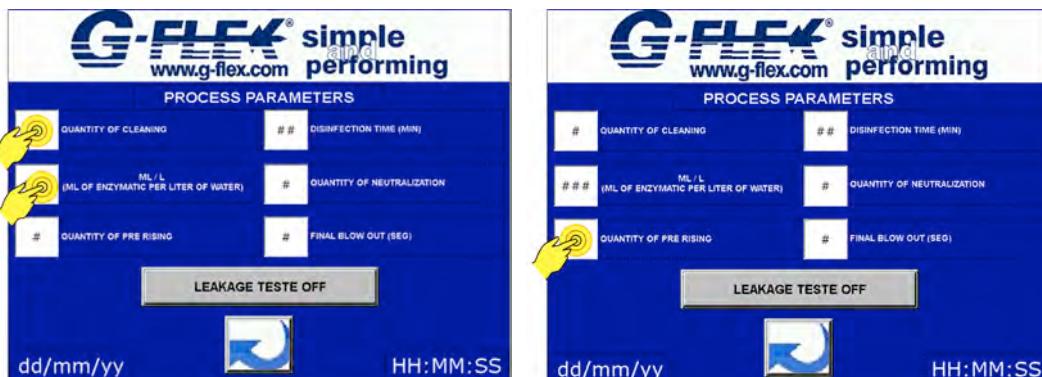
- To configure the parameters of each procedure tap the button from the main screen and select Process.



- Set the parameters that will be executed.

- Quantity of Cleaning
- Quantity of Enzymatic per liter

- Quantity of Pre rinsing



Concentration of solution	0.5%	1.0%	2.0%	3.0%	5.0%
Concentrated Enzymatic detergent [ml]	75 ml	150 ml	300 ml	450 ml	750 ml
Quantity of Enzymatic per liter [ml]	5 ml	10ml	20ml	30ml	50ml



- Disinfection Time



- Quantity of Neutralization



Caution

- Please follow the manufacturer's instructions exactly when preparing the disinfectant solution and observe the specified concentration and exposure times.
- If the exposure time is too short the disinfection process will be negatively affected while a long exposure time can damage the endoscope

- Time for Final Blow Out



- Leakage Test

- Disable Leakage Test



- Enable Leakage Test

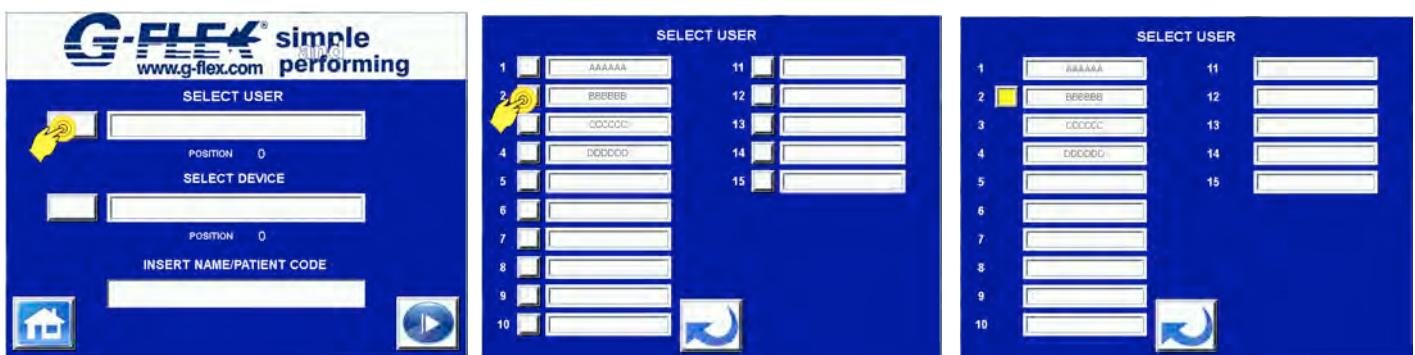


Starting Process

- After all the parameters were configured correctly and all the Users and Devices were registered, tap the START Button to initialize the process.



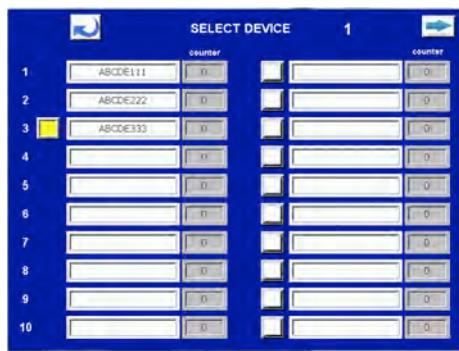
- Tap the button next to the text box to select an user.
- Choose the User and press the return button.



- To the same steps to select the Device.



- Insert the name or patient code and tap the button  to start the procedures that were already configured.



- Check if all the procedures that were set before will be executed. The procedure that were not selected will have the expected time equal zero.


Note

- The Process Status screen will show the expected time for each procedure and the total time of the disinfection process.
- The current time will show the elapsed time of each procedure.


Caution

- If the alarm "Malfunction in suction channel" or "Malfunction in air/water channel" shows at the Process Status screen, this means that the channel monitoring device has detected that the pressure in the biopsy or suction channel or in the air/water channel is too high.
- For information on repairing the fault please refer to the "Error and warning messages" section.





Caution

- The maximum water pressure in the mains water tube should not be more than 5 bar, but should be more than 2,6 bar. If the pressure is greater, install a pressure reducer.



Finishing process

- After all the procedures were concluded. A CONFIRM button will be enabled to finish the disinfection process.
- To print the result of the disinfection process tap the PRINT button or tap the HOME button cancel the print.
- Or to save in a USB storage device (USB Flash drive), tap the USB button



- The print label structure.

HOSPITAL: ABCD	
User:	ABCDEFGHIJKLMNP
Device:	ABCDEFGHIJKLMNP
Patient:	ABCDEFGHIJKLMNP
PROCESS	
LEAKAG TEST OFF	
Cycles	Qtd. TIME
CLEANING	12 12 min 12 s
PRE RISING	12 12 min 12 s
DISINFECTION	12 min 12 s
NEUTRALISATION	12 12 min 12 s
TOTAL TIME	12 min 12 s
DISINFECTION LIFE TIME	12 / 12 / 1234
MACHINE CYCLES	12345
HH:MM:SS	MACHINE: 0000 mm/dd/yy





Note

- To remove the endoscope from the **SCOPE-CLEANER S20** it is essential to use new disposable gloves to prevent recontamination of the endoscope through e.g. germs from the user's skin. We would urge you to ensure thorough disinfection of the hands.
 - Remove the connection tubes from the endoscope.
 - Remove the endoscope from the tank.



Note

- During the course of the day it is perfectly sufficient to blast with air to clear the liquids from the channels. However, at the end of the day, the endoscope and all its channels must be thoroughly dried.



Note

- Because the endoscope control head contains cavities (depending on the model) there may be residual fluid in the suction and air/water valve.
 - Hold the endoscope control head with the valves facing down. Remove the valve covers and shake out the remaining fluid.
 - Finally blow out all the channels carefully with compressed air until they are dry. We recommend using compressed air (up to a maximum of 0.5bar).



Note

- We recommend using a compressor to generate exactly the correct compressed air pressure. The individual steps for final drying of the endoscopes with compressed air can be found in the instructions issued by the manufacturer of the endoscope or the Operating Instructions supplied with the compressor.
 - Wipe dry the outer mantle of the endoscope using a disposable cloth.
 - Carry out a functional test of the endoscope.
 - After this step, the endoscope can be used for examining patients again.
 - For storage purposes, the endoscope must be completely dry, protected from dust, preferably stored hanging in a special endoscope cabinet.
- After the process were finished and any of the Parameters Disinfection need reconfiguration. Just tap the START button to initialize a new process.



Caution

- Only thorough drying can guard against recontamination during storage.



- Dry the valves and store them in a dust-free space.
- Do not refit the valves in the endoscope during storage.

Canceling process

- To cancel or stop the disinfection process, tap the CANCEL button. The unit will ask if you want to stop the process.
- Choosing to stop, the unit will coordinate the Cancel process opening the drain or the tank valve automatically.
- The drain or the tank valve will remain open waiting the user confirms if the coordinating process were finished.



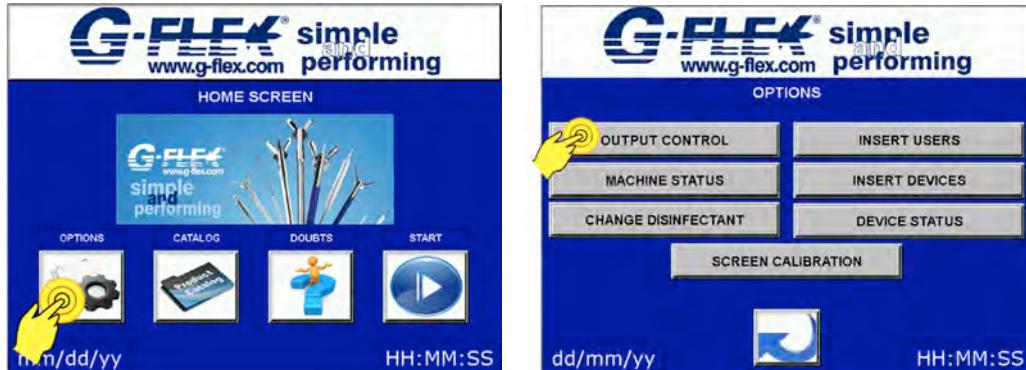
Note

- If the tank is not completely emptied. It is possible to open the corresponding valve with the manual control at the Output Control in the Options menu.

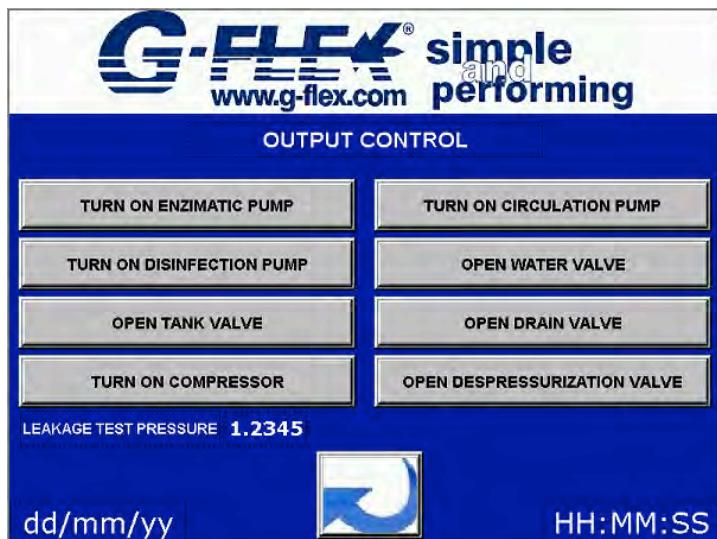
Output control

The Output control is a menu that allows the user to enable all mechanical parts of the unit.

- Tap the OPTIONS Button from the main screen and select the OUTPUT CONTROL Button.



- Each button enable/disable an action.



- When the Compressor is enabled, the Depressurization valve will open automatically when the pressure is above the limited of the sensor.



- If the **SCOPE-CLEANER S20** were switched off when it is full or if there is a power outage while it is in use, it will be necessary, when the unit is switched on again, to drain off the fluid in the tank manually by selecting the Output Control menu to coordinate manually the valves.



Changing the Disinfectant

The **SCOPE-CLEANER S20** will alert of the need to change the disinfectant. The alert is enabled when the maximum number of cycles or the expiration date of the disinfectant are reached. All the disinfectant parameters are configured by the user.

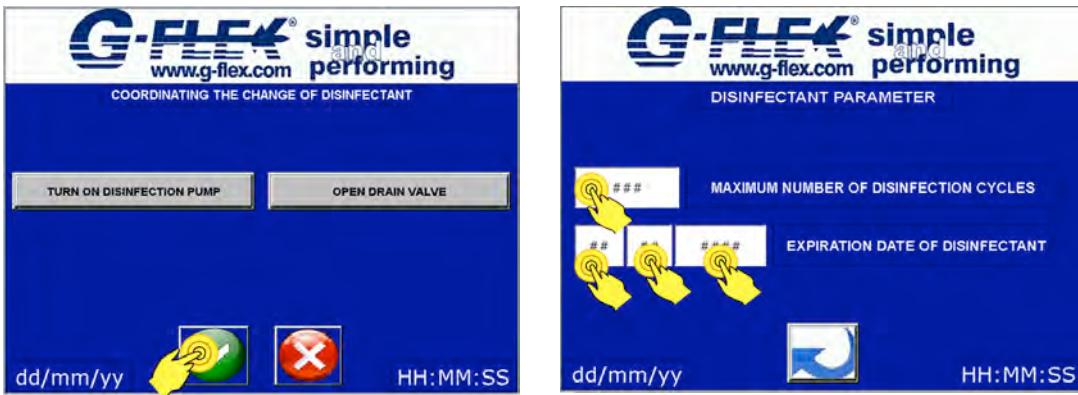


Note

- Please follow the manufacturer's instructions exactly when preparing the disinfectant solution and observe the specified concentration and exposure times.
If the exposure time is too short the disinfection process will be negatively affected while a long exposure time can damage the endoscope.
- At Options menu, tap the Change Disinfectant button.
- The unit will ask if you really want to start the procedure.
- The user will manually turn on the disinfection pump and open the drain valve to discard the solution.



- After finishing the coordinating process, tap the CONFIRM button. It will open the Disinfectant Parameter's screen.
- Set the new parameters to finish the procedure.



Status of the SCOPE-CLEANER S20 and unit information's.

- To see the status of the unit, tap the MACHINE STATUS Button from the Optional Menu.
- At the Machine Status screen there are information about the expiration date of disinfectant, the next date to replace the pre-filter and the sterile water filter, the date to autoclave the sterile water filter, quantity of disinfectant cycle and machine cycles and the work hours of the unit.



- To see the **SCOPE-CLEANER S20** information, tap the MACHINE INFORMATION Button from the Configuration Menu.



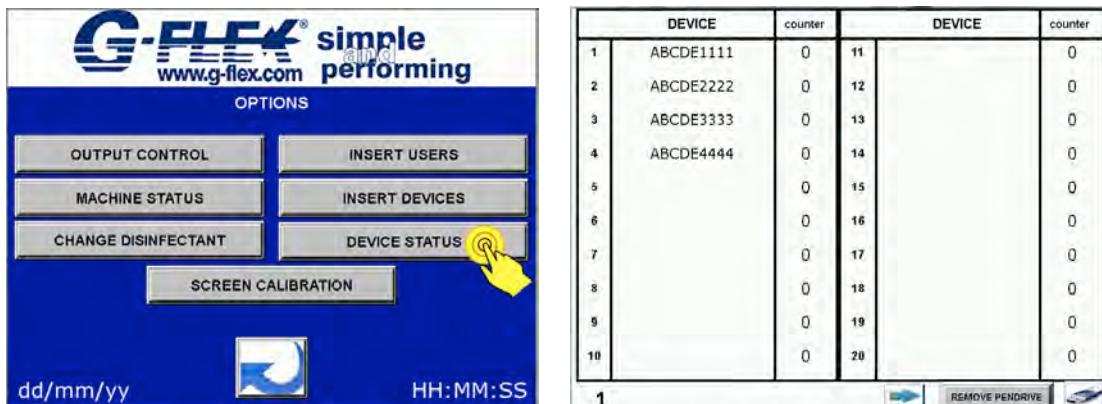
Device Status on SCOPE-CLEANER S20.



Note

- The devices registered in the SCOPE-CLEANER S20 are stored in the internal database of the unit.
- Each position has a cycle counter that reports the number of times each device were reprocessed by the unit.

○ To check the device's status, tap the Device Status button at the Options menu.





Note

- The Device Status screen shows the device code and the quantity of reprocessing cycles.
- It is possible to save the data in an USB storage device (USB Flash Drive).



Nota

- The device counter helps to manage the device's maintenance. Every time that the device is replaced or returned of the maintenance job, we suggest to clear the cycle counter.
- To clear the counter, select the Insert Device button at the Options menu and tap the Clear Counter button of the device.

5. Service and maintenance

Daily cleaning

- Clean and disinfect the disinfection tank and lid thoroughly at least once per working day after use and after every period of 12 hours if not used, and then dry the tank and lid properly.



Caution

- If the disinfection tank and lid are visibly soiled, the unit should be cleaned more often.
- If the lid is not sufficiently cleaned, this can result in the disinfection tank becoming recontaminated.
- Do not use aggressive detergents or solutions containing alcohol to clean the **SCOPE-CLEANER S20** housing. To clean the outer housing, use only a damp cloth together with a paint-friendly cleaning and disinfectant (observe the instructions issued by the manufacturer of the cleaner and / or disinfectant). The tank and lid must be disinfected with a surface disinfectant.

Weekly

Disinfectant solution



Note

- We recommend that the disinfection solution in the disinfectant reservoir be changed at least once a week but if colonoscopes are reprocessed, this should be reduced to every day or every second day.





Caution

- If the disinfectant is visibly soiled or if the disinfectant manufacturer specifies otherwise, the solution should be replaced more frequently.

Sterile water filter



Note

- The sterile water filter and the filling tube and silicone hose must be resterilised every 7 days in a suitable autoclave which meets the requirements of EN 13060, Process Cycle B, i.e. one which allows a fractionated vacuum process.
- The sterile water filter may only be resterilised 10 times. The number of times it is resterilised is entered in the Service Manual (see Appendix).



Caution

- The maximum of 10 resterilisation processes and reuse of the filter are based on historical values where the drinking water used is of normal quality (DIN 38409: carbonate hardness 7 - 21 °dH (water hardness rating of 2 or 3), substances in suspension < 10 mg/l, TrinkwV 2001: opacity < 1.0 NTU). Where the mains drinking water is known to have a relatively high level of particles in suspension or rust particles, it will be necessary to monitor the filtering effectiveness of the sterile filter to be sure.
To have the actual level of contamination tested, please contact a professional plumber or G-Flex Europe SPRL or a service technician authorised by us.
- The degree of efficiency of the sterilisation effect of the sterile water filter, filling pipe and silicone hose depends on the function and parameters of the steam sterilising unit. According to EN 13060, the function and program cycle of the autoclave will be checked and logged.



Dismantling the sterile water filter and preparation for sterilisation:

- To remove the sterile water filter from the **SCOPE-CLEANER S20** pull back the knurled sheath on the quick-release coupler located on the lower connection port (filter intake) and pull the filter up and out.



- Disconnect the silicone hose and filling pipe from the filter outlet.



- Unscrew the air discharge valves on the side of the filter by one turn each. (Caution: liquid will exit the unit due to the existing water pressure!)
- Pour out the residual water from both the intake and outlet.

It is not necessary to blow out the residual moisture in the filter using compressed air. On the contrary, doing so might damage the filter membrane.



Sterilising the sterile water filter

- Place the filter, feed pipe and silicone tube in suitable sterile packaging (paper, sheet, pouch or sterilisation container).
- Place the packaged filter, feed pipe and silicone tube in the autoclave.
- Select the appropriate sterilisation cycle based on the information set out below:

Temperature	Pressure	Temperature-holding time
121°	2,1 bar	20 min
or		
134°	3,1 bar	5 min

- If sterilisation is performed outside the institute, we recommend using double film outers to prevent the normal outer package from being contaminated.



Caution

- Sterilisation of the sterile water filter, filling and silicone tubes should be validated according to the recommendations of the Robert Koch Institute.

Storing the sterilised instruments



Note

- Depending on the kind of sterile packaging, it is possible to store the water filter, filling pipe and silicone hose for up to six months in a protected, dust-free, environment (refer to DIN 58946, DIN 58953-7+8, DIN EN 868-5).
- The storage times should not exceed manufacturer's recommendations.



Assembling the sterile water filter



Caution

- To ensure the sterile water filter remains free from bacteria while in storage there should be no contact with the filter intake and discharge.

Assembly must be carried out under aseptic conditions. In this connection, we would remind users to ensure they disinfect their hands thoroughly.

- Attach the sterile water filter to the **SCOPE-CLEANER S20** water intake making sure that the arrows on the outside of the filter are pointing in the direction of the water flow.
- Pull back the knurled sheath to open the quick-release coupler on the **SCOPE-CLEANER S20** water intake.
- Press the filter intake against the quick-coupler and press it into position.
- Slide the sheath up until it clicks into place.
- Pull the filter to ensure it is fitted correctly and firmly.
- Slide the silicone hose over the filter outlet.



Every 2 weeks

Suction filter

- Replace the suction tube filter in the disinfecting tank, as well as the suction filter in the disinfectant reservoir, every 14 days.



Caution

- Use only original G-FLEX filters as these are calibrated specifically to the **SCOPE-CLEANER S20** flow volume.



Warning

- The prescribed semi-annual and annual services are essential to ensure that this unit works correctly! We recommend you sign a service agreement with G-Flex Europe SPRL or a service technician authorized by us. This will ensure that all the semi-annual and annual services listed in Appendix V are carried out at the required time. If these regular services are not performed, the warranty on the parts to be serviced will lapse.

Dirt trap

- Check the water intake dirt trap at least once a year for soiling and remove any blockages that may be forming.

Pipes & tubes

- Both the tubes inside the unit and the connection tubes in the tank must be replaced once a year.

Up to 6 months

(corresponding to DIN 1988 – depending on water quality)

PALL prefilter (change the filter cartridge, if one is used)

- Open the housing and remove the filter cartridge.
- If necessary, clean the housing.
- Remove the new filter cartridge from its packaging and insert it into the housing.





Note

- The maximum operating temperature of the liquid to be filtered must not exceed 40°C. Higher temperatures may diminish the ability of the strainer or even cause damage to the strainer and housing.

Processing the connection tubes



Note

The connection tubes may only be used after they have been processed (cleaning / disinfection / sterilisation).

Cleaning

Detach the connection tubes from the disinfection unit and the endoscope after the endoscope disinfection process.

Make up a cleaning solution in accordance with the instructions supplied by the manufacturer of the cleaner in a suitable tank.

Submerge the connection tubes totally in the cleaning solution.

Clean the connection tubes using a brush to remove all visible soiling and residues.

Rinsing off the cleaning solution

Thoroughly rinse the connection tubes in a tank of clean tap water and blast them out with compressed air to dry them.

Disinfection

Make up a disinfection solution in accordance with the instructions supplied by the manufacturer of the disinfectant in a suitable tank. Suitable disinfection solutions are aldehydic solutions, amine derivatives and disinfection solutions based on oxidation, e.g. peroxyacetic acid.

Please only use approved disinfection solutions.

Immerse the cleaned connection tubes totally in the disinfection solution and ensure that all the tubes are completely filled inside with disinfection solution and without any air bubbles.

Ensure the soak times given by the manufacturer of the disinfectant are adhered to.

After the disinfection process, remove the connection tubes from the disinfection solution.



Blowing out the disinfection solution

Blow out the inside of the tubes with sterile compressed air.



Caution

Wear protective gloves and goggles!

Final rinse

Place the disinfected connection tubes in a tank of water which is sterile and microbiologically stable.

Rinse the connection tubes thoroughly inside and out with microbiologically stable, sterile water.

DRYING

Blast the insides of the connection tubes with sterile compressed air until fully dry (recommendation: 0.5 bar). Wipe off the outsides of the tubes with a new, disposable wipe.

Sterilisation

Seal the dried tubes in a suitable sterile packaging.

The connection tubes can be autoclaved at 134°C (3 bar) for a period of 5 minutes.



Note

After processing of the connection tubes has been completed and before they are used again, they must be checked to see they are functioning correctly.

The processing of the connection tubes is subject to the following criteria:
After processing, connection tubes must be transparent and flexible. Take careful note of the surface of the tubing. Minor discolouration is acceptable. If major changes are visible in the surface structure or roughness compared with a new connection tube, the tube must be replaced with a new one.

Leaky and porous tubes must be replaced immediately.

The number of reprocessing activities must be recorded.



6. Error and warning messages

➤ Tank Full



- The message indicates that the level sensor is activated when the unit is not performing any process. Tapping the alert message, it will open the Output Control's screen. The user can coordinate the valves to discard or to return the solution to the tank.

Autoclave Sterile Water Filter





- The message indicate that the date to autoclave sterile water filter arrived. Tapping the alert message it will open the Filter Parameter's screen. The user can update the dates.

➤ Replace Pre filter



- The message indicate that the date to replace Pre filter arrived. Tapping the alert message it will open the Filter Parameter's screen. The user can update the dates.

➤ Replace Sterile water filter



- The message indicate that the date to replace sterile water filter arrived. Tapping the alert message it will open the Filter Parameter's screen. The user can update the dates.

➤ **Disinfectant's expiration date**



- The message indicates that the disinfectant expired. Tapping the alert message, the user can start the process to change the disinfectant.



➤ Self-Disinfection



- The message indicates the necessity to perform the self-disinfection process.



Note

- The Warning messages from the Main Screen will not allow the user to start any process while the warnings were not solved. The exception is the Self-Disinfection alert.
- After the changes or corrections were solved, tap the warning message to change the parameters and enable the START Button.



Alert message during the process

Leakage test Error



- This message indicates that the endoscope did not pass at the Leakage Test.
- Please check the endoscope

Excessive time to fill



- The time to fill the tank is longer than expected.

Malfunction in Suction Channel

PROCESS STATUS			
	EXPECTED	CURRENT	
MALFUNCTION IN SUCTION CHANNEL			
TOTAL TIME	17 : 30	17 : 30	
CLEANING	0 : 0	0 : 0	
PRE RISING	4 : 30	4 : 30	
DISINFECTION	6 : 0	4 : 11	
NEUTRALISATION	7 : 0	0 : 0	
LEAKAGE TEST PRESSURE	0.0000 Bar		
05/21/2013			16:57:28

- Increase pressure in the suction channel.

Malfunction in Water/Air Channel

PROCESS STATUS				
	EXPECTED	CURRENT		
	min	s	min	s
TOTAL TIME	17	: 30	17	: 30
MALFUNCTION IN WATER/AIR CHANNEL				
CLEANING	0	: 0	0	: 0
PRE RISING	4	: 30	4	: 30
DISINFECTION	6	: 0	4	: 11
NEUTRALISATION	7	: 0	0	: 0
LEAKAGE TEST PRESSURE	0.0000	Bar		
05/21/2013			16:57:28	

- Increase pressure in the water/air channel.



Failure - Dosage of Enzymatic

PROCESS STATUS					
	EXPECTED		CURRENT		
	min	s	min	s	
TOTAL TIME	17	: 30	17	: 30	
CLEANING	0	: 0			
DOSAGE OF ENZIMATIC FAILURE					
PRE RISING	4	: 30	4	: 30	
DISINFECTION	6	: 0	4	: 11	
NEUTRALISATION	7	: 0	0	: 0	
LEAKAGE TEST PRESSURE	0.0000	Bar			
					
05/21/2013			16:57:28		

- Error during the dosage of enzymatic



7. Troubleshooting

Problem / Error	Cause	Troubleshooting
Filling pump: no or too low filling power...	Blocked filter in the tank section	Exchange the filter of the tank (min. all 14 days)
	Coupling of the suction tube is not locked / snapped into place	Lock / snap into place the coupling of the suction tube
	Suction tube to the tank is buckled	Remove the zigzag of the suction tube to the tank
Rinsing pumps: no or too low rinsing power...	Suction filter in disinfection tank is pulluted	Exchange the suction filter of the disinfection tank (min. all 14 days)
	Complete blackout of one rinsing pump	Call technician
Foam formation in the disinfection tank...	O-ring (black rubber ring) on the coupling connector of the suction tube (tank) absent or defective	Replace the O-ring on the coupling connector of the suction tube (tank)
	Tank is not filled with disinfection solution → pump takes air	Fill the tank with disinfection solution
	Wrong filter inlay in suction filter to tank	Replace the wrong filter inlay in the suction filter to tank by an original filter inlay
Overflow of the disinfection tank...	Foreign substance blocks the vent for the return line, fluid rinse through the return tube in the disinfection tank	Remove the foreign substance and clean the vent
	Neutralization solution does not drain fast enough, water stands in the disinfection tank and the filling pump is already filling the disinfection tank with disinfection solution	Check the drain tube for blockades and rectify them
Fluid in the disinfection tank decrease...	The vent of the drain is blocked, so fluid in rinsing into the drain	Remove the foreign substance and clean the vent
Fluid in the tank is disappears completely after a cycle...	Return tube is buckled.	Remove the zigzag in the return tube



Water does not rinse thru the sterile water filter into the disinfection tank...	Water supply is turned off	Turn on the water supply
	Filter is blocked completely	Exchange the filter (min. all 14 days)
	Filter is not snapped in correctly in the fast coupling	Snap in the filter in the fast coupling
	Wastewater filter is not setup in correct direction	Correct the direction of the wastewater filter (shown by arrows on the filter)
Warning message: EXCESSIVE TIME TO FILL (at the Process Status Screen)	Line pressure is below 2.6 bar (must be: min. 2.6 bar – max 5 bar)	Contact the company technician to set up the line pressure of the water supply to the requested pressure between 2.6 bar and 5 bar
	Sterile water filter is not deaerated	Deaerate the sterile water filter by first opening the lower screw on the filter until water rinse out, the close the screw again. Repeat this secondary with the upper screw.
Warning message: DOSAGE OF ENZYMIC FAILURE (at the Process Status Screen)	No flow of enzymatic into the tube	Check if the enzymatic tank is empty or if the tube is not blocked
Warning message: MALFUNCTION IN THE SUCTION CHANNEL OR WATER/AIR CHANNEL(at the Process Status Screen)	Increase pressure in the channels (Suction or Water/Air)	Check in the tube is not curled. If is not, the endoscope could be obstructed
	The monitoring sensor is not working properly	Call technician

Applicable to all error messages:

If the error cannot be remedied using the steps listed above, please contact G-Flex Europe SPRL or a service technician authorised by us.



8. Technical specifications

Main supply, nominal	230 V or optional (230 V-115 V)
Mains frequency	50 - 60 Hz
Fuses	T 3,15, IEC 127 (2 pieces)
Max.power input	650 VA
Max.power consumption	3,75 A / 2,5 A
Protection class	I
Dimensions (incl.floor cabinet) width x depth x height	770mm x 520mm x 1100mm
Dimensions (without.floor cabinet) width x depth x height	770mm x 520mm x 480mm
Weight (incl.floor cabinet)	approx. 42 kg
HMI supervisory system with touch screen interface	7"
PLC (Programmable Logic Controller)	32K/OEM
Min. Pressure water connection	2.6 bar
Max. Pressure water connection	5 bar
Scavenging pump capacity	500 to 600 ml/min (Distal end of endoscope)
Operating conditions ambient temperature	10°C to 35°C
Operating conditions relative humidity	max. 70%
Classification according to 93/42/EEC	II b (15 EG-RL,93/42/EEC, Appendix IX)
Electrical safety	complies with EN / IEC 61010-1
EMC	complies with EN / IEC 61010-1-2
Capacity of tray	14,5 liters to completely immerse the endoscope, preventing cross-contamination
Capacity of disinfectant tank	15 liters and external to the unit, making it easier to regular cleaning
Capacity of Enzymatic tank	5 liters and external to the unit, making it easier to regular cleaning
Scavenging channels	5 additional channels with individual pumps each
Leakage Test	250 mbar
Inlet water	Without contact with the tray, avoiding contamination of the water supply
Particle retention filter	metallic filter in the tray and in the disinfectant tank
Traceability	Print label or storage data in the USB flash drive
Operational cycles	Quantity and time programming: Cleaning, Prerinsing, Disinfection and Neutralization.
Self-disinfection cycle	Self-disinfection time configured by the user (min 1 hour; max 12 hours)
Disinfectant solution	Compatible with disinfectant: Glutaraldehyde 2%, Orthophthalaldehyde and Peracetic acid
Process Alerts (audible and visual)	increasing pressure /obstruction in the air/water or suction channels; door open; insufficient water, low level of disinfectant, low level of enzymatic, leakage test fail, process concluded
Control Alerts (audible and visual)	exchange the disinfectant solution, filters(pre filter and sterilewater filter)
Sterile water filter	0,2 µ
Database	15 position for users, 80 position for devices (with cycle counter) and unit cycle counter



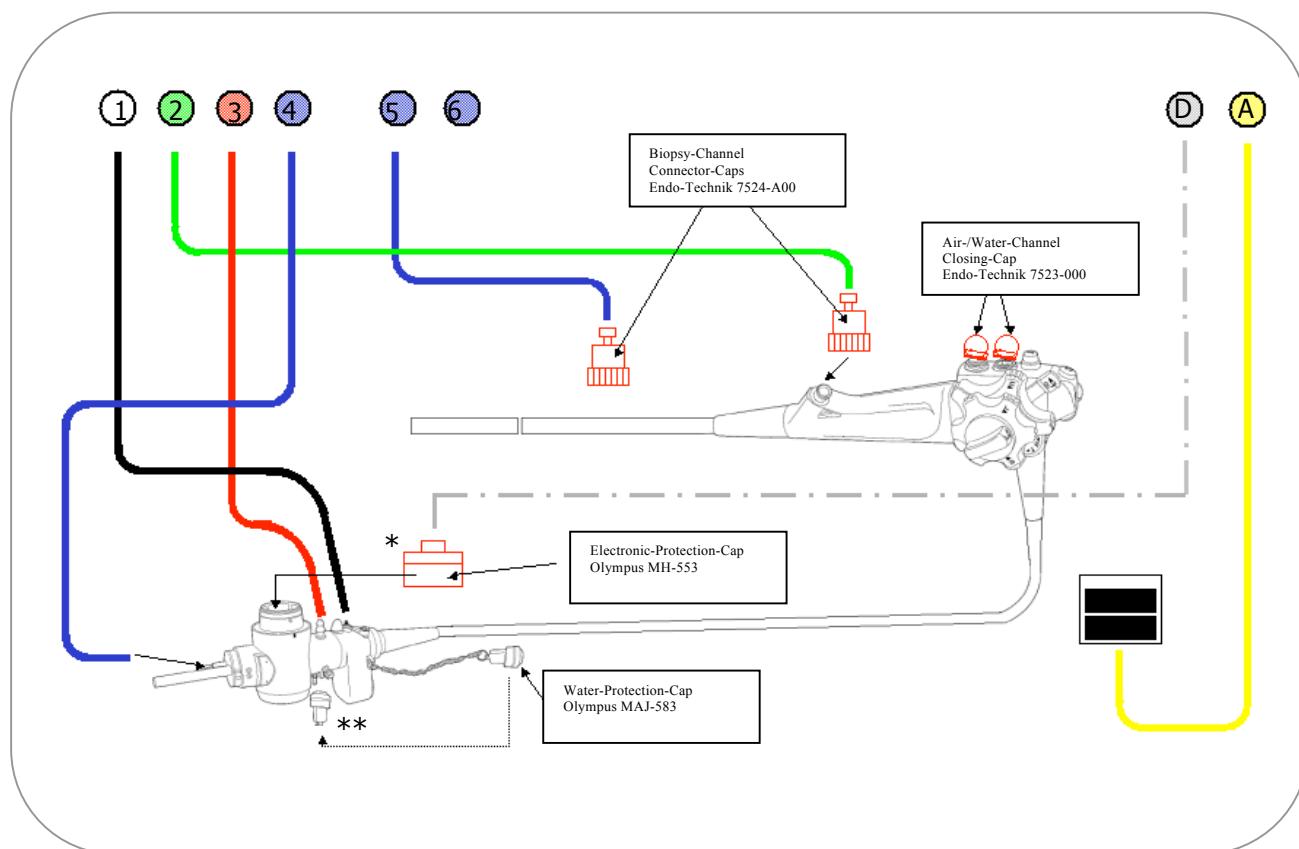
Appendix I:

Connecting to Olympus endoscopes



Note

- If an endoscope does not have a jet channel, ensure the dummy jet channel tube is connected to the **SCOPE-CLEANER S20**.



Number	Channel / Description
1	Jet-Channel
2	Biopsy-Channel
3	Suction-Channel
4	Air- / Water-Channel
5	Biopsy-Channel 2, in Connection with connection caps 7524-A00
6	freei (not all models)
D	Pressure/Leakage Test – Connector
A	Suction Connector Tank

* Add the electronic-protection-cap Olympus MH-553 before you insert the endoscope into the desinfection tank (Pressure/Leakage Test – Connector)

** The water-protection-cap Olympus MAJ-583 must be connected on the water bottle connector.

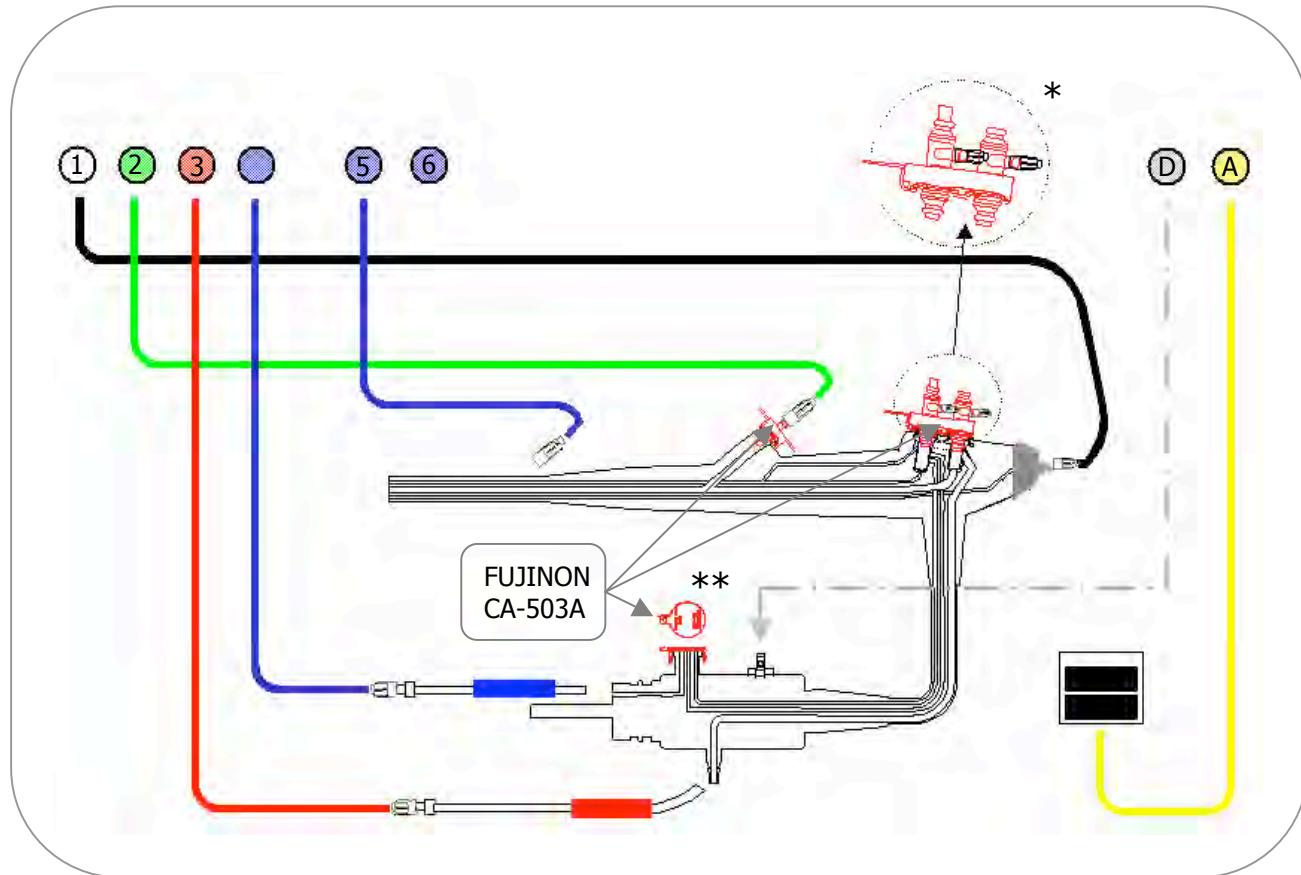


Connecting to Fujinon endoscopes



Note

- If an endoscope does not have a jet channel, ensure the dummy jet channel tube is connected to the **SCOPE-CLEANER S20**.



Number	Channel / Description
1	Jet-Channel
2	Biopsy-Channel
3	Suction-Channel
4	Air- / Water-Channel
5	Biopsy-Channel 2 (Double-Channel, DBE-Balloon-Channel)
6	freei (not all models)
D	Pressure/Leakage Test – Connector
A	Suction Connector Tank

* Fujinon Adapter CA-503 S/A Luer-Lock Connectors ust be closed with caps (see figure)

** Fujinon Waterbottles must be closed!

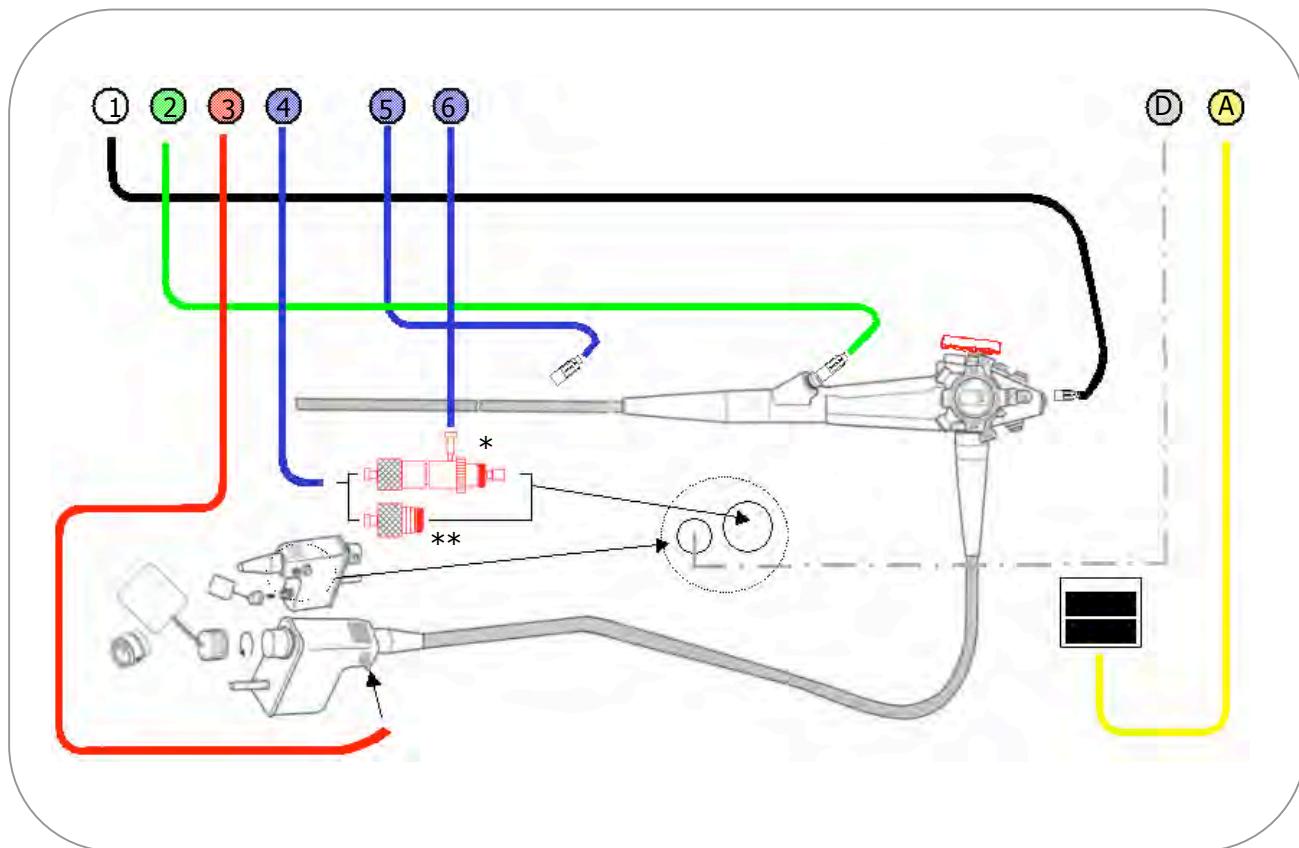


Connecting to Pentax endoscopes



Note

- If an endoscope does not have a jet channel, ensure the dummy jet channel tube is connected to the **SCOPE-CLEANER S20**.



Number	Channel / Description
1	Jet-Channel
2	Biopsy-Channel
3	Suction-Channel
4	Air- / Water-Channel
5	Biopsy-Channel 2 (Double-Channel)
6	Pentax Endoscope Series with separate Air-/Water-Channel
D	Pressure/Leakage Test – Connector
A	Suction Connector Tank

* 7521-100 Adapter for models with single connectors for Air- and Water-Channel

** 7521-000 Adapter for models with Air-/Water-Channel-System



Appendix II

Accessories for SCOPE-CLEANER S20.

Order no.	Description
7600-NS0	Connection set with Nylon-LL suitable for Olympus/Fuji endoscopes comprising: 7600-T00 suction tube with filter 7601-T00 biopsy channel tube 7610-T00 suction channel tube 7611-T00 air/water channel tube
7600-NS1	Connection set with Nylon-LL suitable for use with Pentax endoscopes comprising: 7600-T00 suction tube with filter 7601-P00 biopsy channel tube 7610-T00 suction channel tube 7611-P00 air/water channel tube
7615-100	15 L Tank for disinfection solution with filter and quick coupling in the cover plate



Appendix III:

Spare part list for SCOPE-CLEANER S20.

11-0100	Pall strainer KA2 NFZP4
7006-350	Filling pipe for filter connection
7003-928	Micro fuse 3.15 A
7500-220	Spare metal filter packed in tens
7500-240	Spare metal filter packed in tens for 15 litre tank
7670-E02	SC video disinfection tank incl. LL-connections and level sensor
7680-350	Disinfection lid



Appendix IV

Regular maintenance and cleaning requirements

What	When	Documentation
Cleaning and disinfection of the tank and lid	<ul style="list-style-type: none"> once per working day at the latest after 12 hours of non-use 	in definition by the user
Self-disinfection cycle without an endoscope	<ul style="list-style-type: none"> once per working day at the latest after 12 hours of inactivity or the period set during setup 	in definition by the user
Replace suction filter disinfection filter + tank	<ul style="list-style-type: none"> every 14 days 	at an appropriate location on the unit or nearby, visible for all users and in the User Information Pack
Change the disinfection solution	<ul style="list-style-type: none"> when visibly soiled at the end of a working week at the latest 	at an appropriate location on the unit or nearby, visible for all users and in the User Information Pack
Replace detergent solution for cleaning endoscopes (before reprocessing in the SCOPE-CLEANER S20)	<ul style="list-style-type: none"> if contaminated with organic waste substances, do this immediately after the cleaning process when visibly soiled once per working day at the latest 	no documentation
Sterilisation sterile water filter	<ul style="list-style-type: none"> before first use then every 7 days 	at an appropriate location on the unit or nearby, visible for all users and in the User Information Pack
Filter in the dirt trap	<ul style="list-style-type: none"> annually 	at an appropriate location on the unit or nearby, visible for all users and in the User Information Pack
Pre-filter	<ul style="list-style-type: none"> Latest after 6 month (depending on water quality and contamination of the filter) 	at an appropriate location on the unit or nearby, visible for all users and in the User Information Pack



MAINTENANCE MANUAL

MAINTENANCE MANUAL

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MAINTENANCE MANUAL

MAINTENANCE MANUAL

MAINTENANCE MANUAL

Sterile water filter checked on:

Appendix V

Reprocessing plan

SEMI-MACHINE BASED REPROCESSING OF ENDOSCOPES

CLEANING IN ACCORDANCE WITH MANUFACTURER'S INSTRUCTIONS

PRECLEANING CONNECTED TO THE LIGHT SOURCE

- The outer mantle is wiped off from top to bottom using a saturated lint-free cloth while the endoscope is still connected to the light source
- Draw in copious amounts of enzymatic cleanser alternately via the distal tip and the cleaning adapter
- Operate the air/water infeed for several seconds for each operation
- Insert the cleaning adapter
- Separate the flexible endoscope from the light source

CLEANING IN THE REPROCESSING ROOM

- Carry out a leakage test
- Immerse the flexible endoscope
- Clean all the channels with special cleaning brushes
- Clean the entire air / water system thoroughly
- Flush the channels

REPROCESSING IN THE DISINFECTING UNIT

- The machine must meet all requirements in terms of its ability to ensure cleanliness, disinfection, flushing and drying
- Note:
Before immersing the endoscopes, thoroughly clean and brush all existing channels (instrument channels, water channels, Albaran channels, air/water channel) irrespective of whether they have been used

DRYING

Note:
Wipe off the outer mantle with a disposable, lint-free cloth
At the end of the day, check to see whether all the endoscopes have completely dried and, if necessary, dry the channels with compressed air

STORAGE

Store endoscopes by hanging them in a completely dry, dust-free environment

Follow the manufacturer's instructions to ensure the water bottle is

cleaned



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